Involving newly qualified paramedics in prehospital randomised controlled trials: an analysis of training, enrolment and safety data within the Paramedic Analgesia Comparing Ketamine and MorphiNe in trauma (PACKMaN) study

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Background

Trial background:

The PACKMaN trial is a multi-centre, randomised, double-blinded trial comparing the clinical and cost-effectiveness of ketamine and morphine for severe pain in acute traumatic injury. The study is being conducted in collaboration with the West Midlands Ambulance Service University NHS Foundation Trust (WMAS) and the Yorkshire Ambulance Service NHS Trust (YAS).

Newly qualified paramedic investigation:

Recruitment of participants to the PACKMaN trial was carried out by paramedics following completion of trial training. Both participating ambulance services included newly qualified paramedics (NQPs) for enrolling patients to the study given that NQPs are registered Health Care Professionals and would be required to use the study intervention if introduced into core clinical practice. NQPs are loosely defined as paramedics within their 2 years of training. Pre-hospital research may require ambulance clinicians to randomise patients in time-critical circumstances, while physically remote from senior support available in other clinical settings. There is currently limited evidence around the NQP role and research participant safety.

Aim

To investigate the impact of NQP involvement on participant recruitment, participant safety and protocol non-compliance rates in pre-hospital research.

Methods

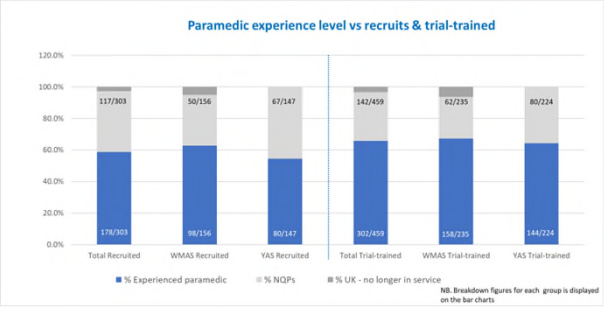
We conducted an analysis of NQP contribution to patient enrolment, which included safety events and incidence of protocol compliances. To do this, the paramedics who recruited a participant were categorised based on their post-registration period as a paramedic: NQPs (within 2 years of training) or experienced paramedics (over 2 years of experience).

Both ambulance services provided the number of participants recruited, trial-trained paramedics, adverse events, serious adverse events (SAEs) and protocol non-compliances (NCs) at their site. Each category was then split by NQP or experienced paramedic. The unadjusted odds ratio between the two experience levels was calculated to investigate whether the incidence of adverse events, SAEs or NCs were significantly different in participants recruited by NQPs versus experienced paramedics.

Results

At the time of investigation, 303 participants had been recruited and 459 paramedics had trained to take part. The investigation revealed that 31% (142/459) of trial-trained paramedics were NQPs and 38% (117/303) of participants were enrolled by NQPs (Figure 1).

Figure 1



Results

Of the participants recruited by an NQP, 43.6% experienced at least 1 protocol-listed adverse event (a secondary outcome measure) versus 44.4% of participants recruited by an experienced paramedic (OR 0.96 [0.59 to 1.59]; p=0.893) (Figure 2). 2.6% of NQP-enrolled participants experienced an SAE versus 2.2% of those enrolled by experienced paramedics (OR 1.14 [0.16 to 6.9]; p=0.861) (Figure 3). Protocol non-compliances were 4 (3.4%) in NQPs and 1 (0.6%) in experienced paramedics (OR 6.27 [0.61 to 310.21]; p=0.063) (Figure 4).

Figure 2

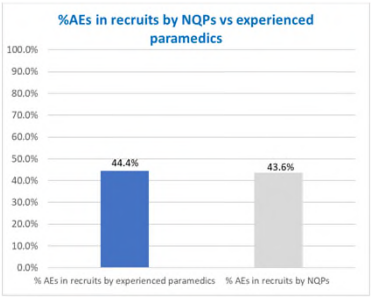


Figure 3

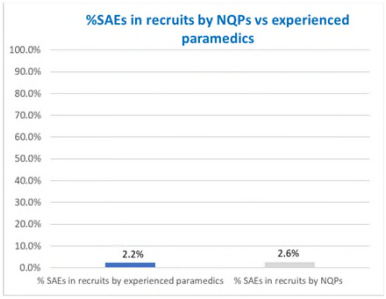


Figure 4

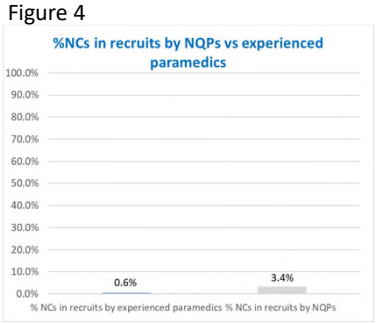


Table 1

	Experience paramedic	NQP	Unadjusted estimate (95% CI); p-value
Adverse Events	79/178 (44.4%)	51/117 (43.6%)	OR 0.96 (0.59 to 1.59); 0.893
Serious Adverse Events	4/178 (2.2%)	3/117 (2.6%)	OR 1.14 (0.16 to 6.9); 0.861
Non-compliances	1/178 (0.6%)	4/117 (3.4%)	OR 6.27 (0.61 to 310.21); 0.063

Conclusion

Newly qualified paramedics made an important contribution to this study, both in terms of participant recruitment, but also in improving the generalisability of study findings across ambulance paramedic practice. We found similar levels of adverse events in participants recruited by an NQP versus by an experienced paramedic. Both the incidence of serious adverse events and protocol non-compliances were infrequent. We found no evidence of safety implications related to including NQPs in this trial. It is important to note that trial training and participation were optional for both NQPs and experienced paramedics and may not be generalisable to research where participation is mandatory.

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Visit the PACKMaN Trial Website: https://warwick.ac.uk/packman